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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,999	03/12/2004	Richard L. Miller	58351US004	8776

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/799,999	MILLER ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of April 13, 2009 made to the office action filed November 12, 2008. Claim 8 is pending.

For the reasons in the previous office action and below, the Applicant's arguments of the following rejections were found not persuasive, thus the rejections are upheld: 1) the 35 USC 112, first paragraph rejection of claim 8; and the 2) 35 USC 103(a) rejection of claims 8 as being unpatentable over Yu et al. in view of Maibach et al.

Due to the no new amendments to the claims and the Applicant's arguments not being persuasive, the previous rejections are repeated below. The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description on how to administer all of the different types of classes of IRM compounds (even those that are TLR7 agonist) other than imiquimod. For instance, the differences in structural features of the different classes of compounds disclosed in claim 8 will result in different reactivity, solubility, bioavailability, etc. Thus, by virtue of the different structures and reactivity of these compounds, the efficacy will inherently be different. One would need to perform further experimentation to acquire the effectiveness and the amounts of each IRM compound in prior art in order to practice the invention. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,335,023 B1) in view of Maibach et al. (US 2003/0072724 A1).

Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders comprising topically applying a topically acceptable vehicle, at least one compound selected from the group consisting of oligosaccharide aldonic acids, and a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42). Cosmetic conditions or dermatological disorders include changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40). The compositions may be formulated as a solution, gel, lotion, cream, ointment, spray, or

other forms acceptable for use on skin (see column 17, lines 49-52). Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42).

Yu et al. does not specifically teach applying imiquimod to treat of wrinkles.

Maibach et al. teaches a treatment of an individual predisposed to or afflicted with skin hyperpigmentation, and comprises topically administering to the individual's affected skin area a pharmaceutical formulation containing a therapeutically effective amount of an agent active for treating skin hyperpigmentation (see page 4, paragraph 44, lines 1-7). A preferred embodiment is the treatment of age spots, which is age-related and hence is common among the elderly (see page 5, paragraph 45, lines 5-8). Active agents include any compound that effectively treats warts such as imiquimod (see page 8, paragraph 92, lines 1-3 and 7). Treatment is to improve or remediate damage, which is exemplified in examples 4 and 5 by the lightened skin regaining essentially normal skin color after eight weeks of treatment (i.e. visibly reducing a skin

change associated with aging and improving the quality of the skin; addresses claims 1, 7, 9 and 10).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and applying imiquimod to treat of wrinkles because of the following teachings: (1) Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40), with a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42); (2) Maibach et al. teaches a treatment for the age related skin condition age-spots or hyperpigmented skin, in which the active ingredient is imiquimod (see page 5, paragraph 45, lines 5-8 and see page 8, paragraph 92, lines 1-3 and 7); and (3) Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42). Thus, one would be motivated to try the treatment of age related skin conditions such as wrinkles with the active ingredient imiquimod, because it also treats the age-related skin condition of age-

spots or hyperpigmented skin, which also results in the fibers of the dermis becoming smaller and sparser with increasing age.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that the present application disclosure provides clear direction to one skilled in the art as to how to practice the claimed invention—i.e. apply a topical preparation of one of the claimed IRM compounds. Many examples within the TLR 7 and/or 8 agonist IRM compound classes listed in claim 8 are disclosed in the patent applications listed in the paragraph bridging pages 3-4 of the specification. Further, one skilled in the art would readily understand that the claimed IRM compounds operate through a common TLR 7 and/or 8 mechanism and how to formulate such compounds for topical administration.

The Examiner disagrees because compounds such as imidazonaphthyridine amine, thiazolquinoline and oxazolopyridine amine have different core structures. And although the compounds "might" have the same mechanism of action, one skilled in the art would need to determine each compound in each class of core structures are efficacious to treat wrinkles. The same mechanism of action does not guarantee effective treatment. It is recognized by those of skill in the art that different strengths of agonists can perform little, a lot or hardly no effect on the desired treatment. Further, each core structure is not known in the art for the treatment of wrinkles, therefore one skilled in the art would not suspect that the broad group of compounds claimed are effective in treating wrinkles. Particularly, the skilled practitioner would have to test

each and every one of compounds as claimed, or at least a subset that is sufficiently representative of the compounds, to determine treatment efficacy for treating wrinkles. For example, to test for the treatment of wrinkles, a particular compound having TLR 7 and/or TLR8 antagonism as claimed in claim 8, would have to be selected, and a suitable dose amount would also have to be selected. If efficacy of the drug did not result, the dosage regime would have to be varied, for example by changing the dosage amount, until efficacy was achieved. If efficacy in the treatment of wrinkles was shown with the particular compound, then another compound having TLR7 and/or TLR8 antagonism as claimed in claim 8 would have to be selected and the process would have to be repeated, including determining the optimum dosage regimen. Once efficacy was established for all or a representative sample of the compounds as claimed for treating wrinkles, the process would have to be repeated. Thus, the skilled artisan would have to undergo exhaustive studies to evaluate each compound having TLR7 and/or TLR8 antagonism for the treatment of wrinkles, in order to be able to fully carry out the invention.

There is no written description on how to effectively treat wrinkles with all of the compounds claimed in claim 8 for the reasons given above. It is clear that the inventors did not have possession of the claimed invention as defined by claim 8 because there is no written description of how to effectively treat wrinkles with the large genus of compounds claimed.

> The Applicant further argues that the Yu et al. reference (US 6,335,023 B1) teaches oligosaccharide aldonic acids for a very wide range of cosmetic an dermatologic purposes, including wrinkles. Yu et al. discloses that various compounds may be combined with oligosaccharide aldonic acids but does not suggest the claimed compounds for the treatment of wrinkles. Yu et al. does not imply that imiquimod works as an anti-wrinkle treatment, but that oligosaccharide aldonic acid would be useful for enhancing imiquimod's known use as an antiviral agent. Maibach et al. does not remedy the deficiencies of Yu et al. because Maibach et al. merely discloses that imiquimod is a treatment for warts – not wrinkles.

The Examiner respectfully disagrees, and notes that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Iimiquimod is a claimed compound to treat skin conditions that improve skin quality (see claims 10, 31 and 42), and Maibach et al. provides the teaching that imiquimod is specifically responsible for treating age related conditions such as hyperpigmentation and age spots (see page 4, paragraph 44, lines 1-7; page 5, paragraph 45, lines 5-8 and page 8, paragraph 92, lines 1-3 and 7). Paragraph 92 is viewed as an active agent of the invention. Thus, the active agent of the invention (treating hyperpigmentation) can be an agent that treats warts or specifically hyperpigmentation. Further, Yu provides motivation for the treatment of wrinkles with imiquimod, as well as the connection between wrinkles and hyperpigmentation. Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and

sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42). Thus, one would be motivated to try the treatment of age related skin conditions such as wrinkles with the active ingredient imiquimod, because it also treats the age-related skin condition of age-spots or hyperpigmented skin, which also results in the fibers of the dermis becoming smaller and sparser with increasing age.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
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